Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12740

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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

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Page ___ of ___

Form Approved OMB No 0910-0291 Expires 12/31/94
See OMB statement on reverse

FDA Use Only
Triage unit
Sequence # 76425
12740

A. Patient information

1 Patient identifier: [redacted] In confidence

2 Age at time of event: 31 or Date of birth:

3 Sex: ☑ female ☐ male

4 Weight: ___ lbs or ___ kgs

B. Adverse event or product problem

1 ☑ Adverse event and/or ☐ Product problem (e.g. defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

☐ death ___ (mo/day/yr)
☐ life-threatening
☑ hospitalization - initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other ___

3 Date of event (mo/day/yr): 5/10/97

4 Date of this report (mo/day/yr): 1/22/98

5 Describe event or problem

Pt. admitted on 5/10/97 c CC of pressure in the chest & nervousness. Was taking "Ripped Fuel", a wt-loss substance obtained from [redacted]. Had been taking x1 week; initially i TID, then ii TID x1 Ripped Fuel contains: Ma Huang Extract 334mg (6% ephedra extract) & guarana extract (910mg, 22% caffeine)/Capsule. Pt. found to have bigeminy & short run of VT, which persisted through 5/15 or later.

6 Relevant tests/laboratory data, including dates

Exit test:
Stage 1 - HR 69, BP 139/85, O2sat 98%
Stage 2 - HR 90, BP 131/86, O2sat 99
Stage 3 - HR 120, BP 114/56, O2sat 100
Stage 4 - HR 84, BP 71/54, O2sat 97

Loss of urinary continence during procedure

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Non-contributory

C. Suspect medication(s)

1 Name (give labeled strength & manufacturer if known)

#1 Ripped Fuel: MaHuang Extract 334mg Guarana Extract 910mg

2 Dose, frequency & route used

#1 i TID x1 wk, PO

#2 ii TID x1 day PTA

3 Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 1wk. prior to admiss

#2

4 Diagnosis for use (indication)

#1 Wt. loss

#2

5 Event abated after use stopped or dose reduced

#1 ☐ yes ☐ no ☐ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

6 Lot # (if known)

#1 ___

7 Exp date (if known)

#1 ___

8 Event reappeared after reintroduction

#1 ☐ yes ☐ no ☑ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

9 NDC # (for product problems only)

10 Concomitant medical products and therapy dates (exclude treatment of event)

Pt. DC'd on atenolol 50mg QD.

D. Suspect medical device

1 Brand name

2 Type of device

3 Manufacturer name & address

RECEIVED JAN 30 1998

4 Operator of device
☐ health professional
☐ lay user/patient
☐ other

5 Expiration date (mo/day/yr)

6
model # ___
catalog # ___
serial # JAN 28 1998
lot # ___
other # MEDWATCH OTU

7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

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E. Reporter (see confidentiality section on back)

1 Name, address & phone #

[redacted]

2 Health professional?
☑ yes ☐ no

3 Occupation: Pharm. D.

4 Also reported to
___ manufacturer
___ user facility
___ distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an X in this box ☐

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

FDA Form 3500-back

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
**The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787**

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